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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,462	03/16/2004	Yougandh Chitre	A04P1025	4009
36802	7590	01/31/2006	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			PATEL, JOY	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/802,462	Applicant(s) CHITRE ET AL.	
	Examiner Joy P. Patel	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/05/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3, 10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Steinemann (US 4,945,342).
2. In regard to claim 1, see Figures 1 and 3. Steinemann discloses a cable (element 1) with an insulated covering (elements 7 and 27) surrounding individually insulated conductors (elements 3 and 23), which are braided together and contain “a solid core having multi-strand cable” (elements 5 and 25). This lead is an electrical cable for performing stimulations and/or measurements inside a human body (see title).
3. In regard to claim 3, Steinemann discloses that the multi-strand cable is composed of a titanium alloy (See abstract, lines 1-9). Steinemann further discloses that many known pacemaker leads are also composed of materials such as MP35N (Column 1, lines 53-60).

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4. In regard to claims 10 and 12, Steinemann discloses, "The cable is preferably provided, on the outside, at least, with electrical insulation consisting of a rubber-elastic, pliable, and bio-compatible material, for example of an elastomer based on polyurethane or silicon" (Column 6, lines 46-49). Steinemann further discloses, "In other respects, the cable 1 is constructed in a way to have a so-called stylet...inserted into the longitudinal opening 9, from its end meant to be connected with the pulse generator. By the use of this stylet, the end of the cable provided with the contact electrode may then be inserted through an artery into the heart of a patient. If the stylet is then pulled out of the longitudinal opening 9, the opening may be closed off...even at the end of the cable 1 adapted to be connected with the pulse generator" (Column 13, lines 17-28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinemann (US 4,945,342) in view of Cobain (5,796,044).

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6. In regard to claims 4-7, Steinemann, as discussed above, discloses a cable comprised of an insulative covering and further comprised of multiple solid-core, "multi-strand" cables, which are braided together and have insulative coverings. However, Steinemann fails to disclose that the "multi-strand" cable is composed of DFT. Steinemann also fails to disclose that the insulative material is composed of a fluoropolymer such as PTFE or ETFE. However it is common in the art to use other materials, such as PTFE (polytetrafluoroethylene) or ETFE, as the insulative material. Cobain discloses, "Effective insulation of the coiled wire conductor surface with a PTFE or ETFE coating would allow the use of these polyurethane materials in lead body outer sheaths" (Column 3, lines 40-42). Cobain also discloses, "The typically used composite conductive material wires are formed with a silver core, to provide increased conductivity, clad with MP35N alloy or surgical grade stainless steel...in a drawn brazed stranded (DBS) or drawn filled tube (DFT) fabrication process well known in the art..." (Column 2, lines 41-46). Therefore, it would have been obvious to one of ordinary skill in the art to modify the Steinemann device to utilize a commonly used fabrication process, such as DFT. It would also have been obvious to one of ordinary skill in the art to modify the Steinemann device to utilize either PTFE or ETFE, both common insulators in the art, as the insulative material. The examiner notes that the applicant does point out that the conductors used in the Cobain reference are coiled conductors. However, a conductive material that is used for the purpose of electrical stimulation can be used irrespective of whether

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the conductor is a "multi-strand cable" or a "coiled conductor" since the conductive properties of the metal would remain the same.

7. Claim 8, 9, 11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinemann (US 4,945,342) in view of Doan et al. (US 2003/0220677).
8. In regard to claims 8 and 9, Steinemann, as discussed above, discloses a cable comprised of an insulative covering and further comprised of multiple solid-core, "multi-strand" cables, which are braided together and have insulative coverings. However, Steinemann fails to disclose that his electrical stimulation/sense lead has a connector, which allows it to be connected to a stimulation device. Doan, on the other hand, teaches an implantable lead that has a connector region so that it can be connected to a stimulation device. Doan discloses, "The lead comprises at least one proximal connector; at least one tissue stimulation electrode; at least one conductor coupled between the at least one proximal connector and the at least one stimulation electrode..." (Abstract, lines 1-6). Doan further discloses, "The cable conductor 70 forms a portion of the electrical connection between the tip electrode 28 and the connector pin 36 at the proximal end of the lead. The other cable conductor 72 provides part of the electrical connection between the sensing ring electrode 30 along the distal portion of the lead body and ring contact 38 on the connector assembly" (Paragraph 55, lines 16-22; See also Fig. 1). Here, elements 36 and 38 are considered by the

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Examiner to be the “terminals” on the connector. The distal tip electrode is element 28, and the “proximally spaced electrode” is element 30. It would have been obvious for one of ordinary skill in the art to modify the device of Steinemann in view of the teachings of Doan, in order to create a stimulation/sense lead that could be connectable to a stimulation device and therefore be put into practice, since the lead cannot function on its own.

9. In regard to claims 11 and 13, Steinemann, as discussed above, disclosed the use of an insulative material such as an elastomer, but never specifically teaches the use of silicone as the insulative material. Doan, on the other hand, teaches, “...and a lead body including a housing of insulating material enclosing the at least one conductor, the lead body having a relatively flexible distal portion of, for example, silicone rubber, having a length corresponding to the coronary sinus region of the heart, and a stiffer proximal portion of, for example, polyurethane” (Abstract, lines 7-12). It would have been obvious to modify the lead of Steinemann in view of the teachings of Doan to have a portion of the lead be composed of silicone and another portion composed of polyurethane, since Steinemann discloses that his lead can also be guided through an artery (See rejection for claim 10). Since both inventions teach a lead for implantation through/in an artery, the teachings of Doan can be applied to the lead of Steinemann.
10. In regard to claim 14, see rejections for claims 1 and 8.
11. In regard to claim 15, see Doan Paragraph 45, lines 1-5.

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12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Steinemann (US 4,945,342) in view of Doan et al. (US 2003/0220677) as applied to claims 8, 11, and 13-15 above, and further in view of Pianca et al. (US 2003/0050681).
13. In regard to claim 16, Steinemann in view of Doan teaches an implantable cardiac lead system that contains conductors with solid cores comprised of multi-strand cable, which are surrounded by an insulative material. However, Steinemann in view of Doan fails to teach the use of an introducer sheath to position the lead appropriately within the heart, in this case, in the coronary sinus. Pianca, on the other hand, teaches a self-anchoring coronary sinus lead that has an introducer sheath "having a first end configured for insertion within a body and a second end extending out of the body. Pianca discloses, "The introducer sheath 600 comprises a main body 610 connected to a tapered portion 620 on one end, and connected to a handle 630 on the other end" (Paragraph 59, lines 3-5). The handle is the region extending out of the body. It would have been obvious to one of ordinary skill in the art to modify the device of Steinemann in view of Doan in further view of the teachings of Pianca, so that the lead could be introduced into the body and positioned properly within the heart.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joy P. Patel whose telephone number is 571-272-5556. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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